American Lung Association.

November 21, 2024

The Honorable Xavier Becerra
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: Advancing Smoking Cessation: Food and Drug Administration (FDA) and National Institutes of Health (NIH) Priorities

Dear Secretary Becerra:

The American Lung Association appreciates the opportunity to submit comments on *Advancing Smoking Cessation: FDA and NIH Priorities*.

The American Lung Association is the oldest, voluntary public health organization in the United States. One of our four strategic imperatives is to create a tobacco-free future, and tobacco cessation is vital to that effort. The Lung Association believes that everyone who uses and is addicted to commercial tobacco products* can quit, not just switch to another tobacco product. Helping people quit their addiction to tobacco is both integral to our mission and is of the upmost national importance. Tobacco use is the leading cause of preventable death and disease in the United States, responsible for the deaths of 480,000 people in the U.S. annually.[1] An additional 16 million people in the U.S. live with a disease caused by tobacco.[2]

The Lung Association is encouraged to see the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) prioritizing tobacco cessation. There is a strong need for additional cessation treatments. Data show that most people who smoke want to quit (67.7%).[3] That same report showed that only 36.3% used medication in their quit attempt and only 8.8% quit. People who use tobacco want to quit but need more treatment options. While the FDA has not approved a new cessation mediation in nearly 20 years, the Lung Association is encouraged by the meeting on October 21and this subsequent comment period, as a signal that the FDA is open to approving new cessation medications.

When looking at tobacco cessation treatment, we urge both FDA and NIH to follow two guiding principles. The first is health equity: any new cessation treatment must strive to reduce health disparities as it relates to tobacco use and tobacco caused disease, not exacerbate them. The second principle is that any cessation product must go through the Center for Drug Evaluation and Research (CDER)'s drug approval process. The Lung Association is deeply troubled about the number of tobacco products that falsely make cessation claims. We urge CDER to ensure any product claiming to be a cessation product is first found to be safe and efficacious.

*References to tobacco refer to commercial tobacco and not the sacred and traditional tobacco that may be used for ceremonial or medicinal purposes by some American Indian communities.

Food and Drug Administration Actions

The FDA can take actions to improve and expand options for tobacco cessation medications and help people in the United States end their addiction to tobacco products. But it is vitally important that the FDA act to help people addicted to tobacco, regardless of whether they use combustible cigarettes, cigars, pouches, e-cigarettes or other tobacco products. It is not quitting if a person switches from using cigarettes to any other tobacco product, including e-cigarettes. There are a number of concrete steps the FDA, specifically CDER, can take to achieve the goals of advancing tobacco cessation.

First, the FDA can create a regulatory environment and pathway that encourages and facilitates responsible companies' efforts to produce and market new and more effective tobacco cessation products. Tobacco kills nearly half a million people every year in the U.S. and the last new cessation product that received an FDA approval was in 2006 - 18 years ago. During this time period, novel tobacco products, including e-cigarettes and pouches, have emerged onto the market, addicting new generations to tobacco, setting them up for a lifetime of addiction and disease.

The FDA should review its processes, including an assessment of barriers that reputable companies face when pursuing the CDER pathway to bring a drug to market. After the review of barriers, FDA should look for ways to ameliorate the barriers.

It is also important to take into consideration that some racial and ethnic minority communities use tobacco and have tobacco-related diseases at higher rates than the general population, including Black individuals. FDA should not purpurate additional mistrust by conflating tobacco products, like e-cigarettes, with cessation products. Companies that have built their businesses around commercial tobacco products and have sued FDA to be regulated as tobacco products[4] are not manufacturers of cessation devices. If these companies want to claim their product helps people who smoke quit, the manufacturer must go through the same CDER process, showing the safety and efficacy of their drug as any other company.

Second, as FDA assesses risks versus the benefits of tobacco cessation products, the FDA must make it clear that continued smoking is the relevant comparator. A recent article from STAT[5] highlighted problems that pharmaceutical companies are facing when working to get FDA approval for smoking cessation medications. The article highlighted the FDA needing additional studies at the last minute and questioning the need for a more effective nicotine replacement therapy (NRT). People who use tobacco products and don't quit continue to be at risk for cancers, heart disease, COPD and many other serious and costly diseases. When looking at approving new cessation drugs, FDA must compare the risks posed by the new cessation therapy to the risks posed by continuing to use commercial tobacco products.

This does not mean the FDA should compromise its safety standards, but instead ensure appropriate consideration for the risks from continued tobacco use. For example, some cancer treatments are toxic and have terrible side effects but are important treatments to stop cancer and save lives. FDA needs to evaluate tobacco cessation therapies that go through the CDER process in the same way it does cancer treatments.

Thirdly, FDA should take affirmative steps to explore alternatives to long-term clinical trials for promising new cessation products or for new indications for existing cessation products where sufficient evidence is available to meet both safety and efficacy. Examples of this are adding an

indication for tobacco cessation products, like nicotine replacement therapy (NRT) to reduce the number of cigarettes smoked each day as part of a "reduce to quit" regime. This can be a point on the path in a person's quit journey and help them quit tobacco for good. Another example of this would be changing the labeling of NRT for combination therapy. This is when a patient is prescribed both short and long acting NRT. For patients that have a very severe tobacco addiction, combination therapy can help them be successful in quitting.

Fourth, FDA should consider modifying its organizational structure by moving cessation products from CDER's Division of Anesthesia, Analgesia and Addiction to another office, such as one that has experience with evaluating treatments caused by tobacco use, such as the Office of Hematology and Oncology Products. Moving cessation products could better facilitate the development of new and innovative products that are both safe and effective. This would also be a signal that FDA is serious about approving new cessation drugs.

National Institutes of Health Actions

NIH also has an important role to play in improving tobacco cessation treatment. The Lung Association urges NIH to prioritize research on what works to help youth (defined as those under 18) quit all commercial tobacco products. There is consensus in the public health community that no person under 21 should use any tobacco product, including cigarettes, e-cigarettes, pouches and other tobacco products. Despite a recent decline in use, 10.1% of high school students report using tobacco products, with the most common being e-cigarettes.[6] The U.S. Preventive Services Task Force has outlined what kind of research is needed to advance youth cessation.[7]

While the American Academy of Pediatrics has created a framework to help pediatricians treat youth addicted to tobacco[8], there is still a limited number of FDA-approve pharmacotherapy treatments available; none of those treatments have FDA approval for use, thus they are only prescribed off-label. Over two million middle and high school kids report using a tobacco product and they need effective treatments to help them quit. However, clinical trials for individuals under 18 are complicated and may not be suited for the private sector. Instead, the Lung Association urges NIH to directly fund such research.

Secondly, the NIH needs to invest in research, for both adults and children, on cessation treatments for tobacco products other than cigarettes. Other tobacco products are addictive and not safe to use. Cessation treatments are needed to help all people addicted to any tobacco product. NIH investment in cessation research would ideally result in more people ending their addictions and lowering their risk of tobacco-related disease.

There are many promising developments for improving tobacco cessation treatments. At the October meeting, researchers talked about promising research on new cessation treatments, including GLP-1 inhibitors. These and other treatments need more research and, if effective, FDA approval for cessation

Tobacco use remains a public health emergency. It is the leading cause of preventive deaths and disease. We urge NIH and FDA to match the urgency that tobacco use and its harms pose to the public's health, working to reduce health disparities as it does so.

Thank you for the opportunity to submit comments on this important issue.

Sincerely,

Harold P. Wimmer
President and CEO

Cc: The Honorable Robert Califf, MD The Honorable Monica Bertagnolli, MD

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[2] U.S. Department of Health and Human Services. The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.
[3] VanFrank B, Malarcher A, Cornelius ME, Schecter A, Jamal A, Tynan M. Adult Smoking Cessation — United States, 2022. MMWR Morb Mortal Wkly Rep 2024;73:633–641. DOI: http://dx.doi.org/10.15585/mmwr.mm7329a1
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[5] Florko, N. Millions of Americans want to quit smoking. Critics say drugmakers and the FDA are failing them. September 23, 2024. STAT. Accessed at: https://www.statnews.com/2024/09/23/smoking-cessation-no-new-class-of-fda-approved-drugs-since-pfizer-chantix/
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[7] US Preventive Services Task Force. Primary Care Interventions for Prevention and Cessation of Tobacco Use in Children and Adolescents: US Preventive Services Task Force Recommendation Statement. JAMA. 2020;323(16):1590–1598. doi:10.1001/jama.2020.4679
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